J35 GCP for Experts

4th November 2020

The day will start at 08:45 with registration and coffee for a prompt start at 09:15. We aim to finish by 17:30.

ICR Training

J35 GCP for Experts

10 CPD POINTS

4th November 2020

J35

Venue -

Course Information

The Course

THIS COURSE WILL TAKE PLACE ONLINE VIA ZOOM

This full-day course provides an in-depth look at the regulatory systems currently in operation in the US and EU and their impact on the conduct of clinical research. The course explains in detail the practical applications of GCP such as risk management, and outlines recent and planned major developments in GCP. It also explores the impact of EU data protection laws on clinical research and provides insight into regulatory inspection approaches as well as "hot topics".

Delegates will receive a complimentary copy of the ICH GCP guidelines and a workbook.

Learning Objectives

- Outline recent and planned major developments in Good Clinical Practice
- Define impact of US and EU regulatory requirements on the conduct of clinical research
- Discuss current issues that affect clinical trials such as sponsor oversight and risk management
- Develop methodologies to prepare efficiently for implementing changes

Course Outline

- US Clinical Trial Regulations
- Declaration of Helsinki
- The Belmont Report
- ICH, including E6, E8, E27 …. and "Renovations"
- The EU Clinical Trial Regulation
- EU Clinical Trials Directives
- UK Clinical Trial legislation
- Voluntary harmonisation procedure
- Data Protection
- GMP Annex 13
- Substantial amendments
- IMPs, NIMPs & auxiliary products
- Inspections and "Hot Topics"

Who would benefit

Experienced clinical researchers with prior knowledge of GCP who wish to gain a more in-depth understanding of the regulatory aspects of clinical research and how to use this in practice.

Course Fees

Guest	**£550.00**
ICR Member	**£450.00**
ICR Member Academic	**£350.00**

Your Trainer

Jeannette Dixon

Jeannette has held GCP quality-focused positions since 2008 at various pharmaceutical companies, and started her own consultancy business in 2017. Prior to transitioning to GCP/GCLP work, she held positions in pharmaceutical training management, project management in Phase I-IV projects, worked as CRA and in academic research laboratories.

Jeannette led quality teams and has extensive experience in Quality Management System (QMS) development, managing audits, CAPAs, risk management and inspection readiness activities as well as in hosting regulatory agency inspections.

Her educational background is a BSc in Medical Sciences, a BSc in Pharmacology, and a Master in Quality Management.

She enjoys travelling, cycling, swimming and painting, and hopes to be able to see a few more deserts in the world…

Pre-Course Questionnaire - To be completed by all delegates

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Please complete and sent to training@icr-global.org or fax to +44 01628 501 709

Course Title: J35 GCP for Experts

Date: 04 November 2020

Name: .....

Company / Hospital: .....

Position / Job Title: .....

How much experience of clinical trials do you have? (Years)

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What are you hoping to get out of the day?

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State one issue/problem you would like discussed at the meeting

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Dietary Requirements

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* The ICR will work with the venue catering team and endeavour to accommodate specific dietary requirements e.g. Vegetarian/Vegan/Gluten Free - however it may not be possible to cover all requests for dietary preferences.

The Small Print

As a matter of policy we do not issue electronic copies of the slides used.

All ICR materials are copyrighted.

All delegates receive a delegate book.

Payment must be received in advance of a training course commencing. The ICR has the right to refuse entry for non-payment. Payment by invoice must be settled within 14 days from the date of invoice.

We understand that occasionally circumstances may change and that you will be unable to attend your chosen course. Notification of cancellation must be made in writing. If you cancel **more than 14 days prior to the event**, we will refund the course less £50 to cover administration costs. If you cancel within 14 days, no refund will be payable, but we will allow you to transfer to another course of your choice.

We will accept a change of delegate at any time without you incurring a penalty. The Institute of Clinical Research reserves the right to cancel any course that is under-subscribed but will give you 7 days notice in writing and will refund your course fees without any liability for any consequential or indirect loss.

At anytime, you may transfer to the same course within 12 months, or to another course of your choice within 6 months; a £25 administration fee will be charged for such transfers.

We may also need to change the venue but will give you 7 days notice in writing of the new location.

Programmes as published are correct, however due to circumstances beyond our control, trainers, speakers and/or the programme may need to be altered occasionally.

The ICR will work with the venue catering team and endeavour to accommodate specific dietary requirements e.g. Vegetarian/Vegan/Gluten Free – however it is not possible to cover all possible requests for dietary preferences.

Registration Form

Please complete and sent to training@icr-global.org or fax to +44 01628 501 709

Registration Form

Please photocopy this form for further registrations

Course Title: J35 GCP for Experts **Course Date:** 04 November 2020

Membership No.: ..... **Title(Dr,Mr,Mrs,etc):** ..... **First Name:** .....

Surname: ..... **Job Title:** .....

Company Name: .....

Email Address: .....

Confirmation of booking will be sent by email, unless you request here that it is sent by post ☐

Correspondence Address

Address: .....

Postcode: ..... **Country:** ..... **Telephone Number:** .....

Special Dietary Requirements

.....

Declaration

I agree to the terms and conditions of booking **Signature:** .....

Method of Payment

Please not that your place will only be confirmed when payment has been received (please tick as required)

I wish to pay the fee of .....

☐ I enclose a cheque payable to "The Institute of Clinical Research"

OR

☐ I wish to pay by

☐ VISA ☐ MASTERCARD ☐ DELTA ☐ EUROCARD

Card Number ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Start Date ☐☐ ☐☐ **Expiry Date** ☐☐ ☐☐

Name (as it appears on the card) .....

Signature of card holder .....

OR

☐ Please invoice my company using Purchase Order Number ☐ Invoices can only be raised when a PO no. is provided

Correspondence Address

Address: .....

Postcode: ..... **Country:** .....